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Eric Miederhoff, Chemical Review Manager
Risk Management and Implementation Branch III
Pesticide Reevaluation Division (7508P)
Office of Pesticide Programs, EPA
One Potomac Yard
2777 South Crystal Lane
Arlington, VA 22202

Re: Chlorpropham - Rationale for Reconsideration of Requirement for Acute Oral Toxicity Test in Passerine

Dear Mr. Miederhoff:

To satisfy the chlorpropham DCI requirement for an acute avian oral toxicity test, PIN NIP, a Division of 1,4GROUP, Inc., authorized Wildlife International to perform dose rangefinding in passerines so that the required test could be properly conducted. Chlorpropham, a solid, was ground to a fine powder and administered to the birds in capsules. Initially, two zebra finch each received a dose of 2000 mg/kg. When both birds regurgitated pieces of the capsules, a second two finches each received 1000 mg/kg. When they, too, regurgitated pieces of the capsule, two canaries were given 2000 mg/kg. One of the two canaries regurgitated pieces of the capsule. Thus, two additional canaries each received 1000 mg/kg. Bothe canaries receiving the 1000 mg/kg dose regurgitated pieces of the capsules. These dose rangefinding results show that it is not possible to perform an acute oral toxicity test at meaningful doses with passerine species.

Attached is a copy of a final report that describes the dose rangefinding effort. You will note that of the eight birds used, two died, most probably from the stress of dislodging and expelling pieces of capsules. Chlorpropham has a fairly strong odor and passerines are known to reject food (e.g., berries, insects) that is odiferous. During this study, the dosed birds were observed twice daily until there were no signs of toxicity for a period of 72 hours. While toxicity was observed immediately after dosing, all of the surviving birds showed normal appearance and behavior from study day 2 until termination on day 7.

The 1996 EPA Chlorpropham Reregistration Eligibility Decision ("the RED") states that a GLP-compliant Bobwhite quail study has been submitted and that "This study indicates that chlorpropham is practically nontoxic to upland game birds." The RED also describes a study conducted with Mallard ducks and states "The data indicate that chlorpropham is practically nontoxic to waterfowl." OCSPP Guideline 850.2100 states that the guideline was developed to obtain data for acute oral toxicity to upland game birds, water fowl, or passerine species. Since chlorpropham has been shown to be "practically nontoxic" to both waterfowl and game birds, the guideline requirement as presently stated has been satisfied.

PIN NIP's chlorpropham is labeled only for indoor use, for the treatment of stored potatoes. Since the product is not labeled for outdoor use, there is minimal opportunity for passerine exposure to the plant growth regulator. Furthermore, the rangefinding study in zebra finches and canaries suggests that, consistent with the results of the

Mallard duck and Bobwhite quail studies, the acute oral toxicity LD_{50} for passerine will also be above 2000 mg/kg, the limit dose.

For the following reasons, PIN NIP respectfully requests a waiver from the requirement to perform an acute avian oral toxicity study in passerines:

- Chlorpropham has been successfully tested for acute avian toxicity in the Mallard duck and Bobwhite quail and, according to EPA, was found to be "practically nontoxic;"
- The applicable EPA Guideline states that acute avian oral toxicity should be determined in upland game birds, water fowl, or passerine species. According to the guideline, this endpoint has been satisfied;
- Wildlife International's dose rangefinding effort in two passerine species shows that an acute avian oral toxicity study cannot be performed in passerines;
- The dose rangefinding effort also showed that should a passerine ingest chlorpropham, the product's noxious odor would cause regurgitation and thus, minimize opportunity for a toxic response;
- The PIN NIP product is labeled only for indoor use;

For the above reasons, on behalf of registrant PIN NIP, I respectfully request that the Agency remove the requirement for an acute avian oral toxicity test from the chlorpropham DCI. Thus, we ask for a waiver from the requirement to perform the acute avian oral toxicity test.

Sincerely yours,

Ralph I. Freudenthal, Ph.D.

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Attachment: Chlorpropham: Acute Oral Toxicity Rangefinders with Zebra Finch and Canary

The attachment: Chlorpropham Acute Oral Toxicity Rangefinders with Zebra Finch and Canary is subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).